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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/775,357 | 02/09/2004 | Eitan Konstantino | 021770-000910US | 1224 |

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| EXAMINER | |
|---|---|
| WILLIAMS, CATHERINE SERKE | |
| **ART UNIT** | **PAPER NUMBER** |
| 3763 | |

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/775,357 | KONSTANTINO, EITAN | |
| | Examiner | Art Unit | |
| | Catherine S. Williams | 3763 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/02/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Objections*

Claim 15 is objected to because of the following informalities: claim 15 depends from claim 12 but refers to "the interventional diagnostic element" which was a limitation of claim 14. It seems that claim 15 should depend from claim 14. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3,6-7 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Miraki et al (USPN 6,248,092). Miraki discloses a catheter body with inflation lumen (10), a balloon (30), an expandable region (34) and a guidewire tube and lumen (40). The proximal end of the guidewire tube is spaced distally at least 1 mm to the distal end of the catheter body. See Figure 1. The balloon has a distal neck portion (36) and proximal neck portion (32 and 12). The proximal neck portion of the balloon is butt joined via connecting member 24 to the distal end of the catheter. See Figure 2. The distal end of the guidewire tube extends distally (42) beyond the distal end of the balloon. The proximal end of the guidewire tube opens through the proximal

neck portion of the balloon at a location (38) distal of the proximal end of the catheter body and so inflation medium can enter the balloon.

Claims 1-4 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Keith et al (USPN 5,370,616). Keith discloses a catheter body with inflation lumen (22), a balloon (26), an expandable region (38) and a guidewire tube and lumen (80). The proximal end of the guidewire tube is spaced distally at least 1 mm to the distal end of the catheter body. See Figure 2. The balloon has a distal neck portion (40) and proximal neck portion (36,24). The proximal neck portion of the balloon is joined over (100) the distal end of the catheter. See Figure 2. The proximal end of the guidewire tube opens through the proximal neck portion of the balloon at a location (92) distal of the proximal end of the catheter body and so inflation medium can enter the balloon.

Claims 1-2 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson (USPN 6,007,517). Anderson discloses a catheter body (2) with inflation lumen (9), a balloon (3) with an expandable region and a guidewire tube and lumen (7). The catheter body (2) is considered to be divided in half between a proximal end region and a distal end region. The proximal end of the guidewire tube (7) is spaced distally of the distal end region of the catheter body. See Figure 1C. The proximal end of the guidewire tube opens through the expandable region of the balloon. See figures 2A,3A,10A and 11A.

Claims 1-4,7-8,11 and 14-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Miki et al (USPub 2004/0267196). Miki discloses a catheter body with inflation lumen (102), a balloon (103) with an expandable region and a guidewire tube and lumen (107). The proximal end of the guidewire tube is spaced and extends distally from the distal end of the catheter body.

See Figure 1. The balloon has a distal neck portion and proximal neck portion. See figure 1. The proximal neck portion of the balloon is joined over the distal end of the catheter. See Figure 1. The distal end of the guidewire tube extends distally (106) beyond the distal end of the balloon. The guidewire tube is spaced distally from the distal end of the expandable region of the balloon by a distance greater than the distance between the proximal end of the guidewire tube and the proximal end of the expandable region of the balloon by a distance less than that of a distal end of the guidewire tube from the balloon.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Miraki, Keith, or Miki individually. All three reference independently meet the claim limitations as described above but each fail to teach the proximal neck portion of the balloon being joined under the distal end of the catheter body.

At the time of the invention, it would have been obvious to make each of the proximal neck portions of Miraki, Keith, or Miki, independently, joined under the distal end of the catheter body. Applicant has failed to state how the joining under versus the other configurations is used for a particular purpose, solves a stated problem or provides an advantage. Furthermore, one skilled in the art would expect the prior art catheters to perform equally well regardless of

whether the balloons are attached in a over, under or butt connection since all connections will result in am inflated balloon that can perform the indicated procedure.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine S. Williams
August 19, 2005